



EUROPEAN PATENT APPLICATION

(21) Application number: 90100236.0

(51) Int. Cl. 5: A61N 1/30

(22) Date of filing: 05.01.90

(30) Priority: 09.01.89 ES 8900058

(43) Date of publication of application:  
18.07.90 Bulletin 90/29

(84) Designated Contracting States:  
DE ES FR GB IT

(71) Applicant: Tomas Justribo, José Ramon  
Paseo Reina Elisenda de Montcada, 13  
E-08034 Barcelona(ES)

(72) Inventor: Tomas Justribo, José Ramon  
Paseo Reina Elisenda de Montcada, 13  
E-08034 Barcelona(ES)

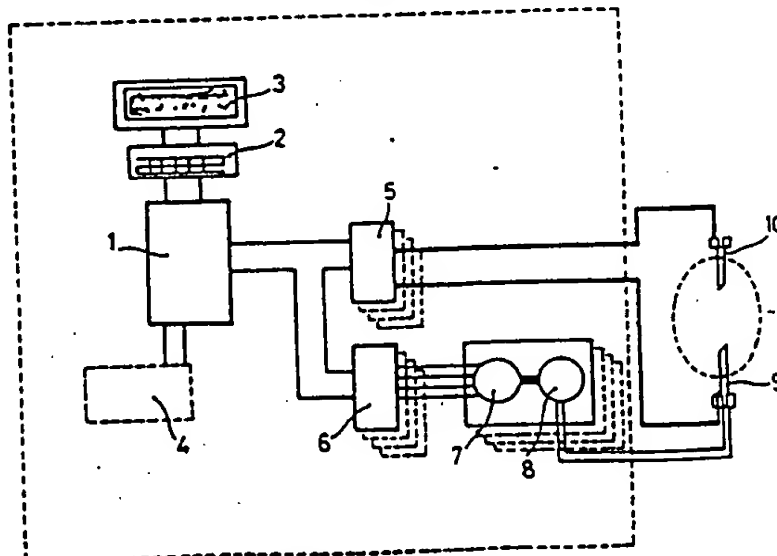
(74) Representative: Kador & Partner et al  
Corneliusstrasse 15  
D-8000 München 5(DE)

(74) Representative: Duran Moya, Luis-Alfonso et al  
c/o DURAN-CORRETJER Paseo de Gracia no.  
101  
E-08008 Barcelona(ES)

(54) A device for the administration of medication by iontophoresis for local - regional treatment.

(57) Equipment for the application, by one or several devices by injection of an active liquid and the simultaneous application of an electric field in the same region, by means of one or more electrodes, controlling the flow and the field intensity as well as the polarity by the use of the said equipment.

FIG.1



## A DEVICE FOR THE ADMINISTRATION OF MEDICATION BY IONTOPHORESIS FOR LOCAL - REGIONAL TREATMENT

At present, as is known, the administration of pharmaceutical products of an active nature to both humans and animals is based on the feeding of these active products into the most appropriate part of the patient's circulatory system whether this be by oral ingestion, by various means of injection or by insertion in the rectum, etc.

One frequently encounters problems in the administration of such medication as is currently known in that the concentration of the active product is insufficiently high in the pathologically affected zone and any increase of the dose in some instances may be dangerous due to the possibility of producing secondary effects in other parts of the organism or even prove to be lethal.

This device is designed to solve these problems by providing a means of controlling the efficient and simple regulation of the pharmaceutically active concentrate in the specific parts of the human anatomy correctly targeted such that excessive levels in other parts of the organism are avoided.

The equipment is applicable to oncology, arthritis and other types of acute or chronic illnesses or infections of a degenerative or other nature.

By way of example, the device can be applied to oncology with the capability of achieving a better cytostatic concentration in the precise locality of the neoplasm, thus obtaining a more effective application of the medication without the difficulties normally met using the usual applicational methods. It is well known that the therapeutic dosage of the cytostatic is at almost the same level as the level of the lethal dosage so that dosage increases cannot be applied following initial satisfactory results, the state of the patient's health not permitting such an increase.

The administration methods used up to now have been the following: oral, intramuscular, intrathecal and finally intravenous by means of a venoclysis. Of all these the last is the most used but exercising a constant vigilance from the haematological point of view, arresting the medication once the haematology so indicates. Reasonably satisfactory results are thus obtained over a long period but nevertheless there remain focuses of neoplasm untreated by the cytostatic so a long term cure is not achieved. Recently the use of Lymphocytes T and K has been tried with truly astonishing results but even in these cases one cannot claim a cure. This treatment however is worthy of consideration given that the application of the device, object of this patent for the administration of cytostatics allows an amplification at the

same time of the immuno-therapeutic treatment, operating in this manner with two distinct methods simultaneously, aggregating the effects and with the same degree of risk for the patient during the disorders of the haemopoietic organs.

This equipment, in principle can be utilized in the case of topographically localized malignant neoplasm and the metastasis including those where the primary locality is not known but are a local regional spread, as well as in other illnesses acting in localized areas.

The object of this invention is based on the injection of a pharmacological substance and the simultaneous creation of an electric field capable of provoking mobile iontophoresis. Both operations must be closely controlled and the equipment must be able to carry them out simultaneously in various pairs of electrode - injection needles producing thus a spread of the substance in a star formation.

The apparatus, object of this invention consists essentially of an electric field generator module, a micro-injection pump module, the injection electrodes and a control processor.

The programmable voltage generator module or modules create an electric field, preferentially three dimensional, by means of one or several electrodes lodged appropriately within or on the patient to be treated. The micro injection pumps introduce one or several medications as programmed, through the electrode injectors, preferably simultaneously or on a dosification and the processor controls to a programme the feed of the injected substance or substances to the required area, this by a control of the intensity and polarity of the electric field created by the electrodes and the regulation of the flow supplied by the injection pumps.

In more detail, the electric field generator comprises a number of identical sub-modules which are programmable as to polarity, voltage, ( between 0 and 60 volts), and current, the polarity being changeable at various frequencies. The equipment must meet the insulation requirements relevant to medical useage.

The sub-modules must be absolutely independent such that spontaneously the polarity and voltage can be varied so as to provide a uniform distribution of the cytostatic substance.

The micro-injection pumps must be controllable from the control unit with a regulation of the flow and volume injected within the range of 0.1 to 5 cm<sup>3</sup> per hour.

The electrode-injectors are in the form of a hyperdermic needle, fully insulated over their entire

mended that the platinum exterior be connected to earth.

The processor must be capable of controlling all the other components, the field generator, the flow and volume of the injected substance as well as the pattern of incidence governing the electric field which dictates the diffusion characteristics of the cytostatic substance in accordance with a programme.

For a better understanding of the patent there are attached hereto, by way of example, drawings showing an explanation of the process and the device for administering pharmacological substances, the object of this patent.

Figure 1 shows in schematic form the iontophoresis equipment, object of this patent.

Figure 2 shows an explanatory sketch of the field generator.

Figure 3 shows a schematic longitudinal section of the active electrode for use with this invention.

As is shown in the above drawings this invention comprises essentially equipment made up of a processor -1- coupled up to a programme entry system -2- for the entry of instructions and a Display unit or screen -3-. A RAM memory operates the data storage and the electric field generator -5- feeds an active injector -9- and the electrode -10-.

The injection pumps -7-, and -8- are controlled by a separate control unit -6-, the object of which is to feed the active injector -9-.

The electric field generator -5- feeds the outgoing leads -11- and -12- and comprises an impulse stage or driver -13- and the isolator amplifiers -14- and -15-. A feedback stage -16- supplies the current and impedance control unit -17-.

The injector shown in Figure 3 comprises an entry mouthpiece -18- extended in a tubular component -19- made from a material which is a good conductor of electricity, covered in a sleeve -20- in an insulating material and having an outer platinum covering -21-. The active fluid passes through the interior of the tube -19-.

Anything not altering, changing or modifying the essential of the device as described is a variable for purposes of this invention patent.

## Claims

1.- A process and device for the administration of pharmacological substances by iontophoresis characterized by comprising the application of one or several components for the injection of active liquid and the simultaneous application of an electric field in the same region, using one or more electrodes and the device regulating the flow as

and the polarity of the same.

2.- A process and device for the administration of pharmacological substances by iontophoresis as in claim 1, characterized in that the apparatus includes one or more programmable voltage generator modules which create an electric field which preferably is three dimensional using one or more electrodes which can be inserted into or attached to the exterior of the patient, a module for programming, preferably both simultaneously or by dosage the injection of one or more pharmacological substances by means of injection pumps and a processor which controls to a programme the movement of the substance or substances in the required region by means of the intensity and the polarity of the electric field created by the electrodes as well as controlling the flow caused by the injection pumps.

3.- A process and device for the administration of pharmacological substances by iontophoresis as in claim 2, characterized by a sequential programmable processor which controls one or more electric field generators which apply a voltage to the electrodes under a controlled form both as to voltage and polarity, these generators being capable of Direct current operation or changing polarity at different frequencies and to dosification units acting on the injection pumps despatching fluid to the active electrodes.

4.- A process and device for the administration of pharmacological substances by iontophoresis as in claims 1 and 2, characterized in that at least one of the active electrodes must be insertable such that it only makes electrical contact with the patient in the zone in which it is required to act, the rest being covered in an insulating material and for preference there being an electrode which does not require to be electrically live, in platinum.

FIG.1

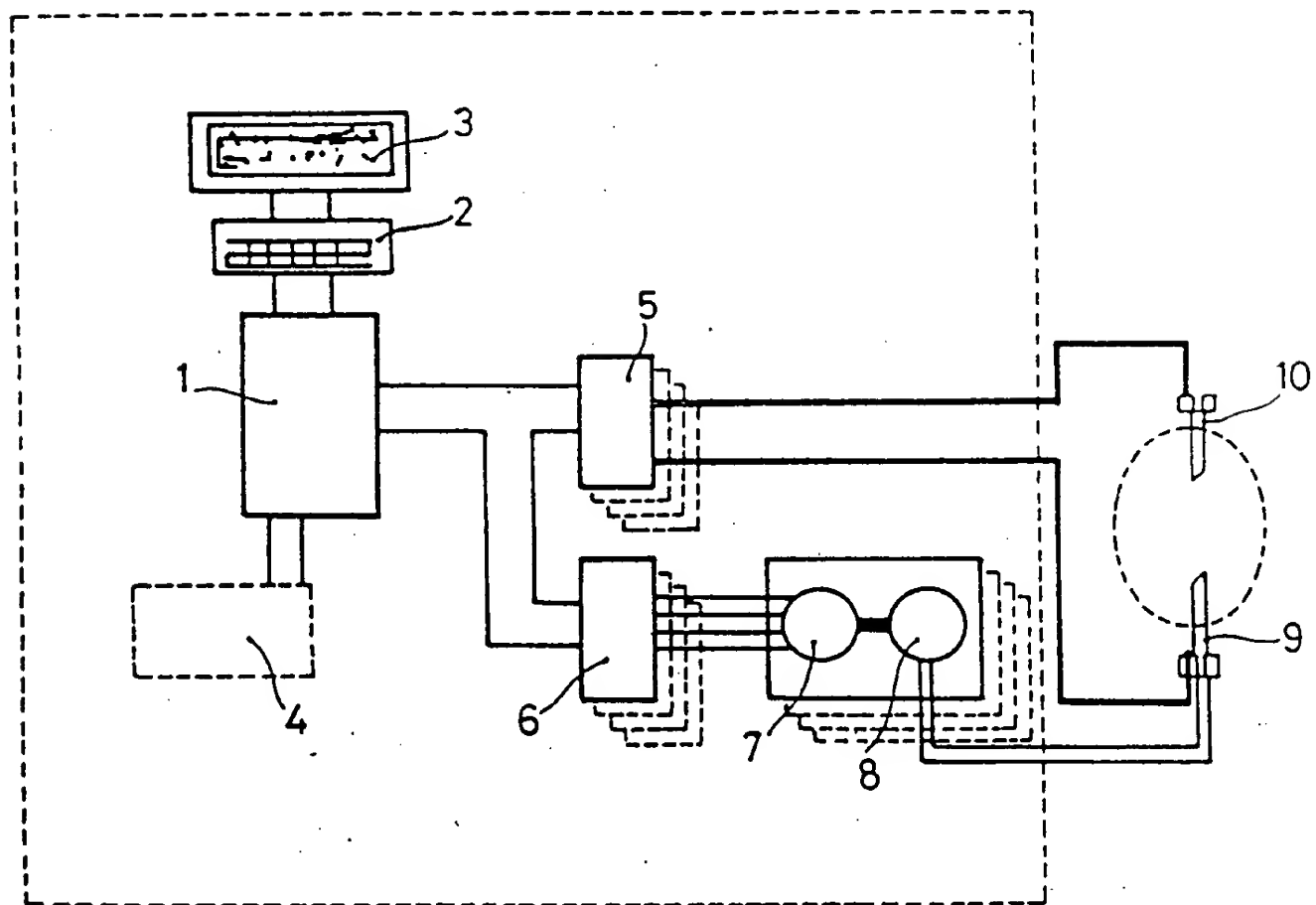


FIG. 2

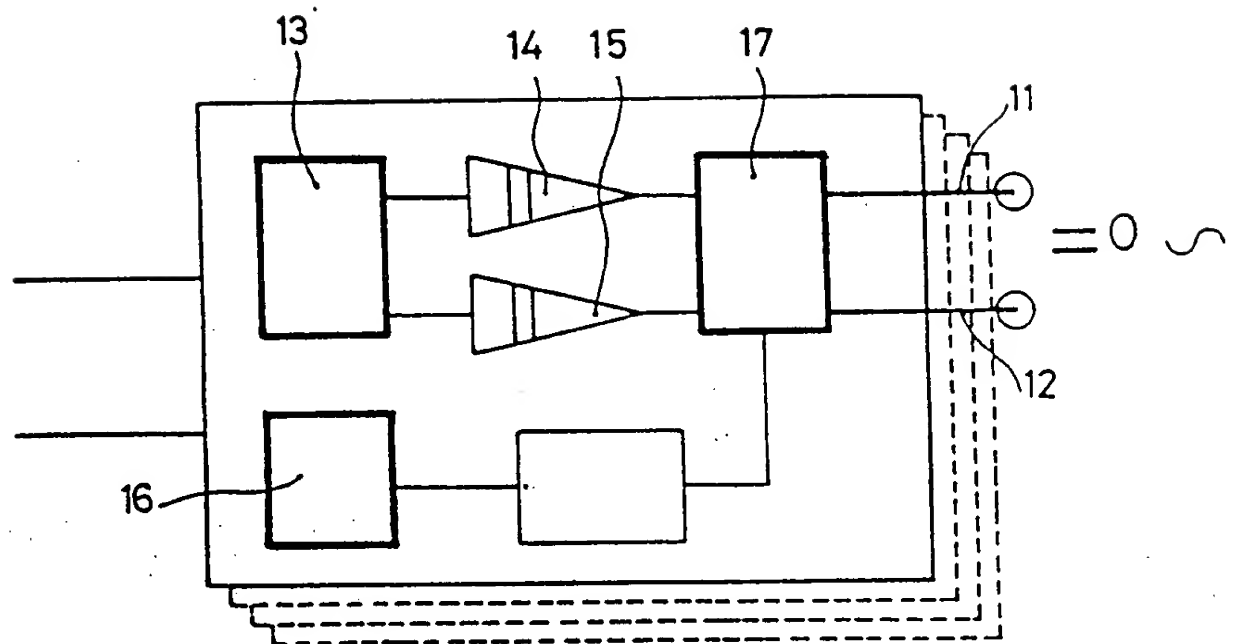


FIG. 3

